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EXAMINER
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ART UNIT	PAPER NUMBER
1638	

DATE MAILED:

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

File Copy

Office Action Summary

Application No.

09/522,334

Applicant(s)

WAGNER ET AL.

Examiner

David H Kruse

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 and 6.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

Drawings

1. The drawings submitted with the application were approved by the Draftsman.

Specification

2. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (see pages; 14, line 21; 20, line 39; 21, lines 1 & 2; 25, lines 7, 9 & 13). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.
3. The use of the trademark GLEAN™ (chlorsulfuron) on page 14, line 8 has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks.

4. In addition, the following informalities were noted:

The use of brackets should be avoided, except for mathematical and chemical formulas. See pages 7, line 12; 9, lines 1, 14 & 15; 10, line 15; 11, lines 25 & 26.

Claim Objections

5. Claims 1, 13, 14, 15 and 19 are objected to because of the following informalities:

At Claim 1, line 10, the step (ii) appears twice in this claim, this appears to be a typographical error at line 10.

At Claims 13, 14 and 15, the term "includes" is confusing, it is suggested that the phrase -- is by -- be used to designate a positive method step.

At Claim 19, line 2, the term "claim" occurs twice. Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claim 18 is rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ novel transformation vectors. Since the transformation vectors are essential to the claimed invention they must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the transformation vectors are not so obtainable or available, the requirements of 35 USC § 112 may be satisfied by a deposit of the transformation vectors. The specification does not disclose a repeatable process to obtain the transformation vectors and it is not apparent if the transformation vectors are readily available to the public.

If the deposit was made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her

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signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit was not made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. § 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

- (a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;
- (d) a test of the viability of the biological material at the time of deposit (see 37 CFR § 1.807); and,
- (e) the deposit will be replaced if it should ever become inviable.

8. Claim 19 is rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a transgenic fruit-bearing plant comprising enhanced expression of a gene encoding SEQ ID NO: 27 or SEQ ID NO: 28, does not reasonably provide enablement for a transgenic fruit-bearing plant comprising enhanced expression of any gene isolated by the claimed method. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant claims a transgenic fruit bearing plant comprising enhanced expression of a gene identified by the method of claim 1, 16 or 17.

Applicant teaches the identification of a nucleotide sequence encoding the amino acid sequences of SEQ ID NO: 27 and SEQ ID NO: 28, isolated by the claimed method (specification, page 25).

Applicant does not teach any other nucleotide sequences isolated by the claimed method.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

The state of the art for plant transformation is such that, "the physiological effects of the transgene on the host plant(s)" are unpredictable (Yuan *et al*, Current Opinion in Biotech., 1997 8:227-233, see Conclusions, page 231). One of skill in the art requires extensive guidance as to the function of a specific gene and the specific requirements to successfully express an isolated gene in a transgenic plant. In addition, Applicant has not demonstrated that transformation of a plant with the identified genes would in fact give the desired phenotype that was selected by the claimed method. Hence, it would require undue trial and error experimentation by one of ordinary skill in the art to identify

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a myriad of genes using Applicant's method, isolate the myriad of putative genes associated with a desired phenotype, transform plants with the myriad of identified genes and identify a transgenic plant exhibiting the desired phenotype.

9. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

10. Claims 1-19 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At Claim 1 line 4, the phrase "an element" is indefinite and does not state the metes and bounds of the claimed invention.

At Claim 1 line 5, the phrase "a termination element" is indefinite and does not state the metes and bounds of the claimed invention. The phrase is interpreted as any element at the terminus of a coding sequence.

At Claim 2 lines 3-4, the phrase "in a manner effective to enhance expression" is indefinite particularly the phrase "in a manner". It is unclear what is encompassed. Does Applicant intend a method where a promoter is operably linked to the gene construct, if the gene construct inserted in a special site in the plant genome or is there another "manner" that is intended?

Claims 4-7 are improperly dependent upon Claim 2 and should be dependent upon Claim 3.

At Claims 5 and 7, the phrase "MV) sequence" should read -- MV) promoter sequence --.

At Claims 8 and 9, the phrase "said selectable marker is" lacks a proper antecedent basis and should read -- said selectable marker-encoding nucleotide sequence encodes --.

Claim 10 is improperly dependent upon Claim 8 because Claim 8 does not recite "antibiotic". Claim 10 should be dependent upon Claim 9.

Claim 12 is improperly dependent upon Claim 10 and thus is indefinite. Claim 12 should be dependent upon Claim 11.

Claims 14 and 15 are improperly dependent upon Claim 12 because Claim 12 does not recite "transforming cells". Claims 14 and 15 should be dependent upon Claim 13.

Claim 16 is in improper Markush format because at line 3 the phrase "minerals, or elements" is improper.

Claim 17 is indefinite and in improper Markush format because of the multiple uses of "and" and "or" in the listing of species.

At Claim 17 line 6, the phrase "root development characteristics" is indefinite because it does not state the metes and bounds of the claimed invention. It is unclear what "characteristics" are encompassed.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1-4 and 19 are rejected under 35 U.S.C. § 102(b) as being anticipated by Hayashi *et al* (Science 1992, 258:1350-1353).

Hayashi discloses a method of identifying genes associated with a desired trait in a tobacco plant comprising transforming a cell with a plant expression vector having an *E. coli* origin of replication, a 4X tandem repeat CaMV 35S promoter sequence and a hygromycin resistance selectable marker operably lined to a nopaline synthase promoter and the polyadenylation signal from gene 4 of T-DNA (see Fig. 1(a)). Hayashi discloses regeneration of identified plants, selfing of identified plants and that $\frac{3}{4}$ of the progeny exhibited the desired trait (page 1352 left column at the top). In addition, Hayashi discloses isolation of the identified gene, construction of a plant transformation vector comprising said identified gene and transformation of tobacco using said transformation vector, thus the transgenic plant at Claim 19 is anticipated (page 1352 left column at the bottom). Hence, all of the claim limitations have been previously disclosed by Hayashi.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 1-19 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Hayashi *et al* (Science 1992, 258:1350-1353).

The teachings of Hayashi are discussed above. Hayashi does not teach promoters and enhancers other than the 4X tandem CaMV 35S promoter, selection markers other than hygromycin, transformation of tissues other than protoplasts, transformation of tomato plants or selection of phenotypes other than auxin-independent growth.

Applicant admits that other plant transformation methods, vectors, promoters and enhancers were known in the art at the time of the instant application including the specifically claimed SEQ ID Nos. and the specifically claimed transformation methods (specification, pages 10-16).

It would have been *prima facie* obvious to one of ordinary skill in the art to modify the method of Hayashi to use other promoters, enhancers, selection markers and transformation vectors. In addition, the selection of a specific transformation method and the desired traits to be selected for would be plant specific. Promoters, enhancers, selection markers and transformation methods are functional equivalents, and the use of such equivalents for a method using a specific plant would be obvious to one of ordinary skill in the art. Also, the specific trait for which one of skill in the art would select for would depend upon what phenotypic traits are desirable in a specific plant. Given the success of Hayashi in identifying a desired trait and isolating genes using the taught method one of ordinary skill in the art would have a reasonable expectation of success in using other promoters, transformation methods and plants to identify desirable traits.

15. No claims are allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Paula Hutzell can be reached at (703) 308-4310. The fax phone number for this Group is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Yolanda Vines whose telephone number is (703) 305-2365.



AMY J. NELSON, PH.D
PRIMARY EXAMINER

David H. Kruse, Ph.D.
5 April 2001